



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request

#### The Stem Cell Therapeutic Outcomes Database OMB No. 0915-0310 – Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for an opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443-9094.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* The Stem Cell Therapeutic Outcomes Database

OMB No. 0915-0310 – Revision

*Abstract:* The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the TRANSPLANT Act of 2021, Pub. L. 117–15 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and for research. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA’s Health Systems Bureau has established the Stem Cell Therapeutic Outcomes Database (SCTOD), one component of the C.W. Bill Young Cell Transplantation Program (Program) which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes to improve the treatment, survival and quality of life for patients who may benefit from cellular therapies. Over time, there is an expected increase in the information reported as the number of transplants performed annually increases, and survivorship after transplantation improves. Similarly, because of ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates incremental changes in information collected by the SCTOD to reflect current clinical care and facilitate statistical modeling throughout the approval period to fulfill the requirements of the Program. Such small incremental changes will not significantly affect the burden.

*Need and Proposed Use of the Information:* Per statutory responsibilities, the collection of information outlined in the “Total Estimated Annualized Burden Hours” section below is needed to collect, analyze, and publish stem cell transplantation related data including patient outcomes data and provide the Secretary with an annual report of transplant center-specific survival data. The proposed revisions of this information collection reflect the most up-to-date medical evidence while simultaneously reducing HCT facility burden. Revisions fall into

several categories: consolidating questions, implementing interactive requests (electronic check boxes, check all that apply, and pull-down menus) to reduce data entry time, adding necessary information fields, adding clarity to information requests and removing items no longer clinically significant (e.g., drugs). These revisions also incorporate COVID-19 vaccine questions currently under emergency approval. From time to time, there may be refinements in the information collection to keep pace with changes in the field or to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records.

*Likely Respondents:* Transplant Centers.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below. The estimated total annual burden hours for this submission are 56,768 compared to 62,583 estimated in the 30-day **Federal Register** notice posted on August 22, 2019.

*Total Estimated Annualized Burden Hours:*

Form Name <sup>1</sup>	Number of Respondents <sup>2</sup>	Number of Responses per Respondent <sup>3</sup>	Total Responses <sup>4</sup>	Average Burden per Response (in hours)	Total Burden Hours
------------------------	------------------------------------	---	------------------------------	--	--------------------

---

<sup>1</sup> This burden estimate table refers to data collections at different time periods consistent with approved practice. The SCTOD contractor is working with respondents to reduce burden by submitting data using interoperability standards. These data collections may include OMB-approved forms.

<sup>2</sup> The Number of Responses the total number of transplant centers that submit data to the SCTOD is equal to 177.

<sup>3</sup> The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

<sup>4</sup> The Total Responses is less than previous calculations because of improvements in estimation. Previous estimates assumed all years had the same number of transplants. This improved estimate includes accurate transplant counts from prior years, which are often less than the current year leading to less follow-up activity.

Pre-Transplant Information Collection <sup>5</sup>	177	46.4	8,207 <sup>6</sup>	1.1 <sup>7</sup>	9,028
Transplant Procedure and Product Information <sup>8</sup>	177	46.4	8,207 <sup>9</sup>	1.0	8,207
Post-Transplant Periodic Information Collection based on Predetermined Schedule <sup>10</sup>	177	319.1	56,476 <sup>11</sup>	0.7 <sup>12</sup>	39,533
<b>Total</b>	<b>177</b>		<b>72,890</b>		<b>56,768</b>

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director,*

*Executive Secretariat.*

[FR Doc. 2022-05718 Filed: 3/17/2022 8:45 am; Publication Date: 3/18/2022]

---

<sup>5</sup> Pre-Transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, and co-morbidities, transplant data procedure characteristics, including preparative regimen, and donor data.

<sup>6</sup> Total Responses for Pre-Transplant Information Collection equals number of new transplant patients in 2020.

<sup>7</sup> This number is rounded to nearest tenth. The actual burden estimate for these data is 1.11666666

<sup>8</sup> Transplant Procedure and Product Information includes Graft-vs-Host Disease (GVHD) prophylaxis, graft source, donor type and degree of human leukocyte antigen matching and graft manipulation; graft characteristic data for cord blood units, including infused cell dose; and product information.

<sup>9</sup> Total Responses for Transplant Procedure and Product Information equals number of new transplant patients in 2020.

<sup>10</sup> Post-Transplant Data Collection includes hematopoietic recovery and engraftment, serious complications including GVHD and second cancers, disease status, survival status, and cause of death; and subsequent procedures.

<sup>11</sup> Total Responses for Post-Transplant Periodic Information Collection is based on a predetermined schedule: 100 days after transplant, 6 months after transplant, 1 year after transplant, annually for 6 years after transplant and then biennially thereafter. In any given year the number of responses is a function of the number of transplants in that year, the number of transplants in previous years, and expected patient survival between the time of transplant and any follow-up activity.

<sup>12</sup> This number is rounded to nearest tenth. The actual burden estimate is 0.74